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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/078,768	06/16/1993	RICHARD H. TULLIS	PMB9658	9155

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EXAMINER	
MARTINELL, JAMES	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/078,768	TULLIS, RICHARD H.	
	Examiner	Art Unit	
	James Martinell	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *64-76 and 78-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64-76 and 78-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 December 1990* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 71 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,023,243. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of U.S. Patent No. 5,023,243 is a specific embodiment of the generic method of claim 71 in the instant application. See also the decision of the Board of Patent Appeals and Interferences, May 17, 2006, pages 8-10.

Claims 64-68, 70, 72-76, and 78-83 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8, 10, 11, and 14 of U.S. Patent No. 5,023,243. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of U.S. Patent No. 5,023,243 is a specific embodiment of claim 64 of the instant application. Claim 65 depends from claim 64 and adds the limitation that the entire sequence of the oligonucleotide is complementary to a protein-coding part of the target mRNA. Claim 1 of the '243 patent requires the use of an oligonucleotide having a sequence complementary to part of the protein-encoding sequence of the target mRNA. The claim does not require that the oligonucleotide have any sequences other than the sequence complementary to the protein-encoding sequence of the target mRNA. One of ordinary skill in the art would have found it obvious to use an oligonucleotide having a sequence that is entirely complementary to part of the protein-encoding sequence of the target mRNA. Thus, instant claim 65 is

not patentably distinct from claim 1 of U.S. Patent No. 5,023,243. Claim 66 depends from claim 64 and adds the limitation that "the oligonucleotide is at least 14 bases in length." Claim 2 of the '243 patent depends from claim 1 and adds the limitation that "said oligodeoxyribonucleotide comprises at least 14 nucleotides." In this context, bases and nucleotides are synonymous. Claim 2 of the '243 patent is a specific embodiment embraced by instant claim 66. For the same reason, claim 3 of the '243 patent is a specific embodiment of instant claim 67. Claim 68 depends from claim 64 and adds the limitation that "the oligonucleotide is between 14 and 23 bases in length." As discussed above, claims 2 and 3 of the '243 patent recite oligodeoxyribonucleotides that are at least 14 and about 23 nucleotides long, respectively. These patent claims would have suggested the limitation of claim 68 to one of ordinary skill in the art. Thus, claim 68 is not patentably distinct from claims 2 and 3 of the '243 patent. Claim 70 depends from claim 64 and adds the limitation that the target mRNA "encodes a hormone." Claim 4 of the '243 patent depends from claim 1 and adds the limitation that the "targeted protein is follicle stimulating hormone." The targeted protein in claim 1 of the '243 patent is the protein encoded by the mRNA to which the synthesized oligodeoxyribonucleotide hybridizes. Thus, claim 4 of the '243 patent is a specific embodiment to the method defined in instant claim 70. Claim 72 depends from claim 64 and adds the limitation that the oligonucleotide is an oligodeoxynucleotide. This limitation is met by claim 1 of the '243 patent. Claims 73, 75, and 78 are independent claims that recite basically the same manipulative steps as claim 64, but include the limitation that the oligonucleotide "has enhanced resistance against nuclease enzymes" (claims 73 and 75) or is "stabilized against *in vivo* degradative enzymes" (claim 78). Claim 1 of the '243 patent states that the oligodeoxyribonucleotide is "in the form of a phosphotriester to limit degradation *in vivo*." Since phosphotriester modification is one method of "enhance[ing] resistance against nuclease enzymes" or "stabiliz[ing] against *in vivo* degradative enzymes," claim 1 of the '243 patent is a specific embodiment of instant claims 73, 75, and 78. Claims 74, 76, and 79 depend from claims 73, 75, and 78, respectively, and each adds the limitation that the "oligonucleotide is between 14 and about 23 bases in length." As discussed above in connection with claim 68, this limitation is suggested by claims 2 and 3 of the '243 patent. Thus, claims 74, 76, and 79

are not patentably distinct from claims 2 and 3 of the '243 patent. See also the decision of the Board of Patent Appeals and Interferences mailed May 17, 2006, pages 14-15. Claims 80 and 83 are similar to claim 78, but it contains the added steps of selecting a plurality of base sequences complementary to the target mRNA, providing oligonucleotides that correspond to the selected base sequences, and selection of a preferred oligonucleotide for use in inhibiting expression of the target mRNA in cells. Claim 83 depends from claim 80 and requires only the limitation of synthesizing the oligonucleotide in "bulk" amounts. Since there is no clear demarcation between a bulk amount and anon-bulk amount, this limitation does not affect the application of claims 8, 10, 11, 12, and 14 of the '243 patent under this obviousness-type double patenting rejection. Claims 8, 10, 11, 12, and 14 of the '243 patent are drawn to *in vivo* methods of inhibiting expression of a target mRNA by using oligodeoxyribonucleotides that are first cross hybridized with RNAs from the same or different organisms in order to select a unique oligodeoxyribonucleotide. That the cross hybridization selection step is used means that more than one type of oligonucleotide was necessarily produced, otherwise no selection step would be needed. Thus, claims 8, 10, 11, 12, and 14 of the '243 patent necessarily imply the synthesis of more than one oligonucleotide for potential use in the inhibition method. The methods of claims 80 and 83 are thus, not patentably distinct from claims 8, 10, 11, 12, and 14 of the '243 patent. Claim 81 depends from claim 80 and adds the limitation of the "oligonucleotides are oligonucleotides stabilized against *in vivo* degradative enzymes." Claim 8 of the '243 patent states that "at least a portion of said oligodeoxyribonucleotide being in the form of a phosphotriester to inhibit degradation *in vivo*." Thus, claim 8 of the '243 patent is not patentably distinct from instant claim 81. Claim 82 depends from claim 80 and adds the limitation of the selected "oligonucleotide is between 14 and about 23 bases in length." As discussed above, claims 2 and 3 of the '243 patent recite oligodeoxyribonucleotides that are at least 14 and about 23 nucleotides long, respectively. These patent claims, in combination with claim 8 of the '243 patent would have suggested the limitation of claim 82 to one of ordinary skill in the art.

Claim 69 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 5,023,243 in view of Summerton (J. theor. Biol. 78:

77 (1979)). Although the conflicting claims are not identical, they are not patentably distinct from each other. As with the claims discussed above, claim 69 is generic to claim 8 of the '243 patent in the sense that claim 8 requires use of a phosphotriester-stabilized oligodeoxyribonucleotide, while claim 69 is open to the use of any oligonucleotide. Claim 8 of the '243 patent is also generic in a sense, to instant claim 69. Claim 8 of the '243 patent is directed to a "method of controlling the infection of a host organism by a foreign organism," and recites an oligodeoxyribonucleotide complementary to mRNA from the "foreign organism," while instant claim 69 recites an oligonucleotide complementary to a "viral" mRNA. Summerton teaches a method of treating viral disease by administering a nucleic acid complementary to the viral genome and modified so that it would cross-link with the viral genome (see the abstract). It would have been obvious for one of ordinary skill in the art at the time the invention was made to apply the method of claim 8 using a virus-specific oligonucleotide as suggested by Summerton in order to down-regulate expression of the viral nucleic acid in an infected host. See also the decision of the Board of Patent Appeals and Interferences mailed May 17, 2006, page 16.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

OFFICIAL FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Art Unit 1634
10/15/04